K110953
p1/5

OBS Medical

JUN 15 2011

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SECTION 7 SPECIAL 510(k) SUMMARY

This Special 510(k) Summary provides the following information:

- General information
- A description of the device, including the indications for use and technology;
- Concise summary of the performance testing supporting the submission;

General Information

Trade Name of Device:	"Visensia®"
Establishment Registration Number:	3005768010
Common/Usual Name:	Adjunct to multi-parameter patient monitor
Classification Group:	MHX
Classification Name:	Physiological Patient Monitor (with arrhythmia detection or alarms)
Classification Regulation:	870.1025
Classification Panel:	Circulatory Systems Devices

Submitters Name and Address:

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Manufacturer:

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Device Description

Visensia® software is a computerized analysis software program designed as an adjunct to standard patient monitors or medical information systems. It operates by forming an aggregate score of patient status based on five vital signs; heart rate; respiratory rate; temperature; non-invasive blood pressure and arterial oxygen saturation. The aggregate score, the Visensia® Index, is displayed on a scale of 0-5, with 0 representing the normal end of the scale and 5

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representing extreme physiological deterioration. An audible and visual alert is provided when the Visensia® index exceeds a threshold value for a period of time.
The Visensia® Index is calculated whenever new data is received.

The Visensia® display consists of a combination of the following:

- An identifier for each monitored patient and location
- The Visensia® Index value for each patient (shown as a number, trend or other graphical representation).
- The vital signs for each patient (shown as a number, trend or other graphical representation).
- A status bar area showing the state of the system

Visensia® may also be implemented as a data processing server with no graphical interface.

Substantial Equivalency Similarities

The table below indicates the similarities and differences between the modified Visensia® device and its predicate device.

Feature	Predicate Device: Visensia® with Alert K081140	Modified Device: Visensia® Device K110953	Data Supporting Change
Intended Use	Visensia® with alert is an accessory to multi-parameter patient monitors (bedside, ambulatory, or centralized location) or clinical information systems and is indicated for use by health care professionals with those non-pediatric high dependency care patients for whom multi-parameter patient monitoring has been routine. Visensia® provides the clinician with a patient status index (Visensia® Index) based on a weighted average of five or (four) vital signs namely heart rate, respiration rate, temperature, oxygen saturation and blood pressure. The Visensia® Index is a single measure of a patient's	**Indication/Intended Use** of the modified device as described in its labelling **has not changed** along with the proposed labelling which includes the User Guide, Installation and Configuration Manual, Booklet for Visensia, Case Label and CD Label for Visensia.	None

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	condition and represents how different the patient's vital signs are with respect to normality. Visensia® is an adjunct to and is not intended to replace vital sign monitoring. When a Visensia® alert has activated, it means that the Visensia® Index has reached and/or surpassed the default threshold and indicates that attention should be brought to the patient.		
Alerts	Variable Alert	Same variable alert, but now able to be set for individual bed from the interface by clinicians.	Visensia® Requirements Specification (011-0106-FS), Design Specification (011-0114-DS) and Visensia® V3.1 Summary Report (011-0155-DTR)
Algorithm	Visensia® Algorithm	Visensia® Algorithm re-factored to improve software integrity. No change to the design of the algorithm.	Visensia® Index Specification (011-0107-FS), Visensia® Index Design Specification (011-0143-DS) and Visensia® V3.1 Summary Report (011-0155-DTR)
Data Handling	Continuous and Periodic data selectable as options	Continuous and periodic data definition and rules updated to enable automated handling	Visensia® Requirements Specification (011-0106-FS), Design Specification (011-0114-DS) and Visensia® V3.1 Summary Report (011-0155-DTR)

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	Blood Pressure Scaling is based on Mean and Standard Deviation of SDA	Blood Pressure scaling now depends on whether SDA is above or below the Mean, to take into consideration Hypo-tensive events.	Visensia® Requirements Specification (011-0106-FS), Design Specification (011-0114-DS) and Visensia® V3.1 Summary Report (011-0155-DTR)
	Median Filtering for vital sign values	Median Filtering applied to historical non-periodic data when used alongside periodic data.	Visensia® Requirements Specification (011-0106-FS), Design Specification (011-0114-DS) and Visensia® V3.1 Summary Report (011-0155-DTR)
Labelling	Manuals and Labelling	Updates to Manuals and Labelling to reflect new formatting styles.	Visensia® User Guide (011-0131-LMAN), Visensia® Installation and Configuration Manual (011-0130-LMAN), Booklet for Visensia® V3 Software (011-0127-LMAN), Case Label for Visensia® V3 Software (011-126-LAB) and CD Label for Visensia® V3 Software (011-0125-LAB)

In summary, the OBS Medical Ltd Visensia® product described in this submission is, in our opinion, substantially equivalent to the predicate device (K081140).

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Performance Testing

The following testing has been carried out:

- Unit Testing – has been carried out by developers on individual software modules of the system. Modules are tested in isolation from the rest of the system.

- Integration Testing – has been carried out with all modules integrated in to a single software build. These test that the modules work correctly when integrated and is conducted during the system testing process. This is conducted at this point due to the design of the Software architecture.

- System Testing – has been carried out on the completed product. This includes the full software device operating on representative hardware and communicating with a Philips MP30 patient monitor and an emulated clinical information system.

In summary, all the required testing has been carried out with satisfactory results for the release.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OBS Medical
c/o Ms. Barbara J. Uggen-Davis
Chief Operating Officer
10401 North Meridian, Ste. 300
Indianapolis , IN 46290

JUN 15 2011

Re: K110953
Visensia®
Regulatory Number: 21 CFR 870.1025
Regulation Name: Patient Physiological Monitor (with arrhythmia detection or alarms)
Regulatory Class: II (two)
Product Code: MHX
Dated: May 15, 2011
Received: May 16, 2011

Dear Ms. Uggen-Davis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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SECTION 6 INDICATIONS FOR USE

510(k) Number (if known): K110953

Device Name: **Visensia®**

Indications For Use:

Visensia® with alert is an accessory to multi-parameter patient monitors (bedside, ambulatory, or centralized location) or clinical information systems and is indicated for use by health care professionals with those non-pediatric high dependency care patients for whom multi-parameter patient monitoring has been routine.

Visensia® provides the clinician with a patient status index (Visensia® Index) based on a weighted average of five or (four) vital signs namely heart rate, respiration rate, temperature, oxygen saturation and blood pressure. The Visensia® Index is a single measure of a patient's condition and represents how different the patient's vital signs are with respect to normality. Visensia® is an adjunct to and is not intended to replace vital sign monitoring.

When a Visensia® alert has activated, it means that the Visensia® Index has reached and/or surpassed the default threshold and indicates that attention should be brought to the patient.

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

Prescription Use __X__ AND/OR Over-The-Counter Use_____
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K110953